IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of:		Confirm No:	9497
David K. Kovalic *et al.*		Art Unit:	1631
Appln. No.:	09/684,016	Examiner:	Shubo Zhou
Filed:	October 10, 2000	Atty. Docket:	16517.031
Title:	**Annotated Plant Genes**		

APPELLANTS' AMENDED BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Attn: Mail Stop Appeal Brief - Patents

Sir:

This is an Appeal from the Final Rejection of all claims pending in the above-referenced patent application. A Notice of Appeal was filed on September 17, 2003. An Appellant's Brief was filed November 17, 2003, at which time the statutory fee of $320.00 for submitting an appeal brief was paid. This Amended Brief is submitted in response to the Office Communication mailed March 1, 2004 which alleged that the Brief filed August 28, 2003 was non-compliant with 37 C.F.R. 1.192(c). *This Brief is submitted in triplicate.*

1. Real Party in Interest

The real party in interest is Monsanto Company, a Delaware corporation with offices at 800 North Lindbergh Boulevard, St. Louis, Missouri 63167.

2. Related Appeals and Interferences

Applicants are unaware of any Appeals or Interferences related to this Appeal.

3. Status of Claims

Claims 11-16 are pending. Claims 11-16 stand finally rejected under 35 U.S.C. § 101 as allegedly lacking utility and under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement. Claims 11-15 are rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking written description. Claim 14 stands rejected under 35 U.S.C. §112, first paragraph, as allegedly containing new matter. Claim 13 is rejected under 35 U.S.C. §102(b), as allegedly being anticipated. Applicants appeal all of the rejections of claims 11-16.

4. Status of Amendments

Applicants filed an Amendment After Final Rejection ("Amendment") on July 29, 2003, requesting amendment of claims 13-15. The Amendment was filed in response to the Final Office Action ("Final Action"), which was mailed on June 17, 2003 (Paper No. 15). In response to Applicants' Amendment, an Advisory Action was mailed by the U.S. Patent and Trademark Office on August 27, 2003 (Paper No. 18) ("Advisory Action"), stating that "[f]or purposes of Appeal, the proposed amendment(s) will be entered...."

5. Summary of Invention

The invention is directed to a substantially purified nucleic acid molecule comprising a fragment nucleic acid molecule having from about 30 to about 50 nucleotide residues of a nucleic acid molecule having the nucleotide sequence of SEQ ID NO: 48411. Specification at page 3, lines 12-14; page 8, line 28 through page 9, line 9. The invention is directed to a substantially purified nucleic acid molecule comprising a fragment nucleic acid molecule having from about 50 to about 100 nucleotide residues of a nucleic acid molecule having the nucleotide sequence of SEQ ID NO: 48411. *Id.* The present invention is also directed to a substantially purified nucleic acid molecule comprising a fragment nucleic acid molecule having from about 30 to about 50

nucleotide residues, wherein said fragment nucleic acid molecule exhibits complete complementarity to a fragment of a second nucleic acid molecule having the nucleotide sequence of SEQ ID NO: 48411 or a complete complement thereof. Specification at page 3, lines 12-18; page 8, line 28 through page 9, line 9; page 9, line 30 through page 10, line 4. The present invention is also directed to a substantially purified nucleic acid molecule having between 90% and 100% sequence identity with nucleotides 1 through 123 of SEQ ID NO: 48411 or a complete complement thereof. Specification at page 3, lines 12-18; page 11, line 5 through page 12, line 12; and sequence listing at SEQ ID NO: 48411.

6. Issues

The issues in this Appeal are:

(a) whether claims 11-16 are unpatentable under 35 U.S.C. § 101, as allegedly not being supported by a specific asserted utility or a well established utility;

(b) whether claims 11-16 are unpatentable under 35 U.S.C. § 112, first paragraph for alleged lack of enablement because the claimed invention purportedly lacks utility;

(c) whether claims 11-15 are unpatentable under 35 U.S.C. § 112, first paragraph for alleged insufficiency of written description;

(d) whether claim 14 is unpatentable under 35 U.S.C. § 112, first paragraph for allegedly containing new matter; and

(e) whether claim 13 is unpatentable under 35 U.S.C. § 102(b) for alleged anticipation.

7. Grouping of Claims

Claims 11-16 are pending in this application. All of the claims at issue do not stand or fall together. The separate patentability of claims 11-16 is addressed together in Sections 9.A through 9.C below. The separate patentability of claims 11-15 is addressed

in Section 9.D below. The separate patentability of claim 14 is addressed in Section 9.E below. The separate patentability of claim 13 is addressed in Section 9.F below.

8. Preliminary Remarks

Applicants thank the Examiner for withdrawing the rejection of claim 15 under 35 U.S.C. §112, second paragraph in the Advisory Action at page 2.

9. Argument

A. Summary of Appellants' Position

As the Supreme Court said in *Brenner v. Manson*, the "basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility....where specific benefit exists in currently available form." 383 U.S. 519, 534-35, 148 U.S.P.Q. 689, 695 (1966). Applicants have met their part of the bargain – they have disclosed nucleic acid molecules that, in their current form, provide at least one specific benefit to the public, for example, use to identify the presence or absence of a polymorphism. This benefit is specific, not vague or unknown, and it is a "real world" or substantial benefit. Because the claimed nucleic acids provide at least this benefit, they satisfy the utility requirement of 35 U.S.C. § 101. Because the specification teaches how to make and use the claimed nucleic acids for the disclosed utilities, the enablement requirement of 35 U.S.C. § 112 has likewise been met.

Furthermore, Applicants have provided an adequate description of the claimed nucleic acids that demonstrates Applicants' possession of the claimed invention. Each genus of claimed nucleic acid molecules, *e.g.*, the nucleic acid molecules comprising the nucleic acid sequence of SEQ ID NO: 48411 its complement, and fragments thereof, for example, has been described by the recitation of a common structural feature – the nucleotide sequences of SEQ ID NO: 48411, and its complement, respectively – which distinguishes molecules within the claimed genus from molecules outside of the claimed

genus. Because the specification demonstrates that Applicants have possession of (and have provided an adequate description of) the claimed genera of nucleic acid molecules, the specification satisfies the written description requirement of 35 U.S.C. § 112.

Applicants have provided sufficient written description support in the specification and in the sequence listing such that a new matter rejection is improperly applied to claim 14. The recitation of the range "nucleotides 1 through 123 of SEQ ID NO: 48411" is supported in the specification and in the sequence listing; and the inclusion of such a range in the presently pending claim is validated by *In re Wertheim,* 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). As such, Applicants have met the burden of written description and introduce no new matter by the inclusion of the noted claim language.

Claim 13 was erroneously rejected as anticipated by a reference that fails to teach the recited nucleic acid sequence. The Examiner improperly considered a non-identical chemical compound to anticipate the claims as drawn to a nucleic acid molecule comprising a fragment nucleic acid molecule having from about 30 to about 50 nucleotide residues, wherein said fragment nucleic acid molecule exhibits complete complementarity to a fragment of a second nucleic acid molecule having the nucleotide sequence of SEQ ID NO: 48411 or a complete complement thereof, despite the fact that the cited reference fails to teach such a fragment nucleic acid molecule. The Examiner has asserted an untenable interpretation of claim 13, misconstruing claim 13 and citing a reference that does not anticipate the present claims. Absent a teaching of each and every element of the claims, the reference cited by the Examiner does not anticipate the present claim 13.

B. The Claimed Nucleic Acids Have Legal Utility

Pending claims 11-16 were erroneously rejected under 35 U.S.C. § 101 because the claimed invention was allegedly not supported by either a "specific and/or substantial utility or a well established utility." Final Action at pages 2-3. According to the Final Action, "since the function of the gene comprising the claimed sequence is not known, identifying the presence or absence of a polymorphism in a population is not deemed a real world utility." *Id.*

This analysis misstates the nature of the asserted uses, ignores disclosed utilities, and misapplies the doctrine of "practical utility" developed by the courts after *Brenner v. Manson*. The "threshold for utility is not high: An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). Furthermore, an invention need only provide one identifiable benefit to satisfy 35 U.S.C. § 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983) ("when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown").

The courts have expressed a test for utility that hinges on whether an invention provides an "identifiable benefit." *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366, 51 U.S.P.Q.2d 1700, 1702 (Fed. Cir. 1999), *citing Brenner v. Manson*, 383 U.S. 519, 534 (1966). For analytical purposes, the requirement for an "identifiable benefit" may be broken into two prongs: (1) the invention must have a specific, *i.e.*, not vague or unknown benefit, *In re Brana*, 51 F.3d 1560, 1565, 34 U.S.P.Q.2d 1436, 1440 (Fed. Cir. 1995); and (2) the invention must provide a real world, *i.e.*, practical or "substantial" benefit. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). A corollary to this test for utility is that the invention must not be "totally incapable of achieving a useful result," *i.e.*, the utility must not be incredible or

unbelievable. *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992).

Applicants have asserted throughout the specification that the claimed nucleic acid molecules provide identifiable benefits, for example use to identify the presence or absence of a polymorphism, and use as a marker. *See, e.g.*, specification at page 39, line 29 through page 44, line 2. Either of these utilities alone is enough to satisfy Section 101. Because Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and they have done so in the present case, the premise of the rejection under Section 101 is incorrect, and the rejection should be reversed.

(1) The Claimed Nucleic Acid Molecules Provide A Specific Benefit, *i.e.*, They Have Specific Utility

Applicants have demonstrated that the claimed nucleic acid molecules are themselves useful for utilities disclosed in the specification, *e.g.*, to detect the presence or absence of polymorphisms. *See, e.g.*, specification at page 40, line 4 through page 42, line 13. The specification also discloses additional utilities for the claimed nucleic acid molecules, including, for example, use of the claimed nucleic acid molecules to measure the level of mRNA in a sample,[1] and use as molecular markers.[2] *See e.g.*, specification at

[1] It is standard practice to screen populations of nucleic acids with EST sequences, often attached to a microarray, without characterizing each and every target mRNA. Knowing that the gene corresponding to the claimed nucleic acid molecules is expressed under certain conditions or in certain tissues or at certain levels is in itself useful. For example, such information is useful to detect expression changes in traits of interest.

[2] One can use the claimed nucleic acid molecules to determine location of a corresponding DNA sequence on a physical map or genetic map location without knowing anything beyond the claimed sequence. The use of molecular markers is a practical activity in the development of nutritionally enhanced or agriculturally enhanced crops. Such markers are useful in, for example, genetic mapping or linkage analysis, marker-assisted breeding, physical genome mapping, transgenic crop production, crop monitoring diagnostics, and gene identification and isolation. As more markers are identified, genetic maps will become more detailed and it will be easier for plant breeders to breed for particular traits.

page 39, line 29 through page 40, line 3; page 42, line 14 through page 44, line 3; page 44, lines 11-16.

(a) Identifying the Presence or Absence of a Polymorphism

One of the utilities disclosed in the specification is use of the claimed nucleic acid molecules to identify the presence or absence of a polymorphism. Specification at page 40, line 4 through page 42, line 13. The Examiner argues that this utility is not "a real world utility", *see* Final Action at page 3, but does not provide any support, legal or factual, for the proposition that detection of polymorphisms is not a legal utility. The Examiner's reliance upon the Interim Utility Guidelines has led to an interpretation of utility that contravenes well-established doctrines of utility developed in the courts.

Applicants reiterate that many of the disclosed utilities in this case, including detection of polymorphisms, are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecules may be used to locate and measure nucleic acid molecules within a sample, cell, or organism. The Examiner denigrates this utility by asserting that these uses are not "useful" because allegedly "...further research has to be done...." *See, e.g.,* Final Action at page 3. However, the fact that, for example, a new and nonobvious microscope or screening assay can be used for further learning about products or processes does not lessen the fact that such "tools" have legal utility. Indeed, "Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have clear, specific and unquestionable utility (*e.g.*, they are useful in analyzing compounds)." MPEP § 2107.01 at page 2100-33.

Use of the claimed nucleic acid molecules to detect the presence or absence of polymorphisms is no more legally insufficient than using a gas chromatograph to analyze the chemical composition of a gas – such use determines information about the gas, not the gas chromatograph. Moreover, even if the gas chromatograph detects the absence of

a particular chemical element in the gas, that finding does not obviate the utility of the gas chromatograph itself. Information has been obtained about the gas.[3] Likewise, the claimed nucleic acid molecules have utility even if the absence of a particular polymorphism is detected. Indeed, the absence of a polymorphism usefully demonstrates that the two (or more) populations being compared share a common genetic heritage.

The claimed nucleic acid molecules produce a specific, *i.e.*, not vague or unknown, benefit – they are useful to identify the presence or absence of a polymorphism. This benefit is immediately realized directly from the use of the claimed nucleic acids, not from the use of other molecules. Such a proven use, that provides an acknowledged benefit to the public, satisfies the utility requirement of 35 U.S.C. § 101.

(b) Probes for Other Molecules or Source for Primers

Other uses for the claimed nucleic acid molecules include use as probes for other molecules or as a source of primers. The specification discloses that the claimed nucleic acid molecules can be used, via hybridization, in real world applications, such as for example, to isolate nucleic acid homologues of other plants and organisms including alfalfa, *Arabidopsis*, barley, *Brassica*, broccoli, cabbage, etc.[4] Specification at page 38, lines 5-15. The Examiner has not provided any evidence that would reasonably suggest that this cannot be done, and as such, has not met the burden of proof required to establish a utility rejection. *See In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436,

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[3] For example, gas sampled from crude oil may be analyzed by gas chromatography for the presence or absence of chlorine, which is toxic to catalysts used in gasoline refining even in very low concentrations. The absence of a peak at the molecular weight of chlorine indicates the absence of chlorine in the sample being tested, thereby providing useful information (no chlorine is present, therefore the catalyst will not be destroyed) to the refinery manager. *See, e.g.*, U.S. Patent No. 6,133,740 entitled "Chlorine Specific Gas Chromatographic Detector."

[4] Moreover, one skilled in the art of hybridization and amplification understands how to design and utilize probes and primers to target a sequence of interest, and thus it is not necessary for Applicants to provide a laundry list of each and every nucleic acid molecule that can be identified using the claimed nucleic acid molecules.

1441 (Fed. Cir. 1995). *Accord In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *In re Langer*, 503 F.2d 1380, 1391, 183 U.S.P.Q. 288, 297 (C.C.P.A. 1974).

One illustrative example of a molecule that can be isolated using a claimed nucleic acid molecule is the promoter of the gene corresponding to that claimed nucleic acid molecule. Applicants have specifically disclosed that one use of the claimed nucleic acid molecules is to initiate a chromosome walk. *See e.g.*, specification at page 39, lines 4-16. The Examiner denigrates Applicants disclosed utilities by asserting that they are not "specific." Final Action at page 2-3. In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose, *i.e.*, a chromosome walk. This position is wrong as a matter of law --- there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result..."). Such an argument would imply that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls. That position must be rejected as it requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933).

Moreover, Applicants reiterate that it is factually incorrect that this use is not "specific" to the claimed nucleic acids. The claimed nucleic acid molecules provide a particularly appropriate and demonstrably useful starting point for a walk to isolate a promoter that is active, for example, in *Glycine max*. A random nucleic acid molecule does not provide an equally good starting point to isolate such a promoter. Furthermore,

even if another nucleic acid molecule provided a better starting point than the claimed nucleic acid molecules, it would not obviate the utility of the claimed nucleic acid molecules. An invention may be "less effective than existing devices but nevertheless meet the statutory criteria for patentability." *Custom Accessories, Inc. v. Jeffrey-Allan Indus.*, 807 F.2d 955, 960 n.12, 1 U.S.P.Q.2d 1196, 1199 n.12 (Fed. Cir. 1986).

The Examiner has failed to provide evidence for believing that the claimed nucleic acid molecules could not be so used. Accordingly, the demonstration of utility through use as a probe for other molecules or as a source of primers satisfies the requirements of 35 U.S.C. § 101. *See In re Brana*, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995).

(2) The Claimed Nucleic Acid Molecules Provide Practical, Real World Benefits, *i.e.*, They Have Substantial Utility

It appears that the Final Action is arguing that the disclosed uses are legally insufficient or "insubstantial" under 35 U.S.C. § 101, but such an argument has no basis in law. The touchstone of "substantial" utility is "real world" or "practical utility." *See, e.g., Fujikawa v. Wattanasin*, 93 F.3d 1559, 1563, 39 U.S.P.Q.2d 1895, 1899 (Fed. Cir. 1996). "'Practical utility' is a shorthand way of attributing 'real world' value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public." *Nelson v. Bowler*, 626 F.2d 853, 856, 857, 206 U.S.P.Q. 881, 883 (C.C.P.A. 1980) ("tests evidencing pharmacological activity may manifest a practical utility even though they may not establish a specific therapeutic use").[5]

[5] *Accord Cross v. Iizuka*, 753 F.2d 1040, 1050, 224 U.S.P.Q. 739, 747-48 (Fed. Cir. 1985); *Rey-Bellet v. Engelhardt*, 493 F.2d 1380, 1383, 181 U.S.P.Q. 453, 454 (C.C.P.A. 1974).

There can be no question that one skilled in the art can use the claimed nucleic acid molecules in a manner which provides an immediate benefit to the public, for example, to perform high-throughput microarray analysis of expression changes in a series of tissue samples. The detection of expression changes provides an immediate benefit to the public because, for example, it enables a plant geneticist to rapidly identify relationships or patterns within the expression changes corresponding to various tissues of organisms grown under various different conditions. This comparative information about a plant's expression profile under different growth conditions, like the information about a compound's pharmacological profile in *Nelson*, provides an immediate benefit and thus a practical real world utility to the public.

Quite apart from the analysis of gene expression, there is also no question that the public has recognized the benefits provided by the claimed subject matter, and has attributed "real world" value to such nucleic acid molecules. The utility of ESTs is not merely an academic issue; the real world value of ESTs is self-evident from the growth of a multi-million dollar industry in the United States premised on the usefulness of ESTs. Like fermentation processes involving bacteria, ESTs and nucleic acid molecules with EST sequences are "industrial product[s] used in an industrial process – a useful or technical art if there ever was one." *See, e.g., In re Bergy*, 563 F.2d 1031, 1038, 195 U.S.P.Q. 344, 350 (C.C.P.A. 1977).

The market participants for EST products are primarily sophisticated corporations and highly knowledgeable scientists who are unlikely to pay for useless inventions. *Compare Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 960, 220 U.S.P.Q. 592, 599 (Fed. Cir. 1983) ("People rarely, if ever, appropriate useless inventions"). Quite simply, the commercial value of ESTs is proof of their real world value and of the benefits they provide to the public. This evidence cannot be ignored. The patent system was created to serve and foster growth and development in the industrial arts. If the industries

themselves recognize and appreciate the value of an invention, it is not for the Patent Office to say that they are mistaken.

(3) The Disclosed Utilities Are Credible to One of Skill in the Art

An assertion of utility must be accepted by the Examiner unless it would not be considered "credible" by a person of ordinary skill in the art. MPEP § 2107 at 2100-29. Cases in which utility was found not to be credible are rare, and usually involve "hare-brained" utilities.[6] A challenge to the credibility of a utility is essentially a challenge directed to operability, and such a challenge must be supported by a clear statement of "factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975); *see In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995); MPEP § 2107.02 at 2100-41.

Applicants have explicitly identified specific and substantial utilities, not only in the specification, but in Applicants' Response dated August 8, 2002 at page 6, lines 7 through 14. "To violate [35 U.S.C.] 101 the claimed device must be totally incapable of achieving a useful result." *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571, 24 U.S.P.Q.2d 1401, 1412 (Fed. Cir. 1992). To date, the Examiner has provided no conclusive evidence that the claimed nucleic acid molecules will not work

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[6] Examples of incredible utilities are given in MPEP § 2107.01 at page 2100-34, and include:

> an invention asserted to change the taste of food using a magnetic field (*Fregeau v. Mossinghoff*, 776 F.2d 1034, 227 U.S.P.Q. 848 (Fed. Cir. 1985)), a perpetual motion machine (*Newman v. Quigg*, 877 F.2d 1575, 11 U.S.P.Q. 1340 (Fed. Cir. 1989)), a flying machine operating on "flapping or flutter function" (*In re Houghton*, 433 F.2d 820, 167 U.S.P.Q. 687 (C.C.P.A. 1970)), a method for increasing the energy output of fossil fuels upon combustion through exposure to a magnetic field (*In re Ruskin*, 354 F.2d 395, 148 U.S.P.Q. 221 (C.C.P.A. 1966)), uncharacterized compositions for curing a wide array of cancers (*In re Citron*, 325 F.2d 248, 139 U.S.P.Q. 516 (C.C.P.A. 1963)), a method of controlling the aging process (*In re Eltgroth*, 419 F.2d 918, 164 U.S.P.Q. 221 (C.C.P.A. 1970)), and a method of restoring hair growth (*In re Ferens*, 417 F.2d 1072, 163 U.S.P.Q. 609 (C.C.P.A. 1969)).

for the disclosed utilities. Unless and until the Examiner can prove that the claimed invention is wholly inoperative, the rejection must be withdrawn.

In view of the above, Applicants contend that the claimed nucleic acid molecules are supported by credible, specific, and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities. Consequently, the rejection of claims 11-16 under 35 U.S.C. §101 is improper and should be reversed.

C. The Claimed Nucleic Acids Are Enabled by the Specification

The enablement of the claimed nucleic acid molecules has been challenged. Claims 11-16 have been erroneously rejected as not enabled by the specification, because the claimed nucleic acid molecules allegedly lack utility and therefore cannot be enabled. Final Action at pages 3-4, Advisory Action at page 2. This rejection is erroneous and has been overcome by the arguments stated above regarding utility because it is well-established law that "the enablement requirement is met if the description enables any mode of making and using the invention." *Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1361, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998) (emphasis added), *quoting Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 U.S.P.Q.2d 1300, 1304 (Fed. Cir. 1991). Unless and until the Examiner comes forth with evidence to rebut the objective truth of the utilities disclosed in the specification, this enablement rejection must be withdrawn as improper. *See In re Wright*, 999 F.2d 1557, 1561-62, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993); *Ex parte Lemak*, 210 U.S.P.Q. 306, 307 (Bd. App. 1981) ("pure conjecture" does not substantiate rejection for lack of enablement).

D. The Specification Provides An Adequate Written Description of the Claimed Invention

The adequacy of the written description of the claimed invention has been challenged by the Examiner because the claimed subject matter was allegedly "not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s)...had possession of the claimed invention." Final Action at page 4. The Examiner contends that "the specification only provides sequences of the elected SEQ ID NO: 48411, but not the sequences comprising the sequence of the elected SEQ ID NO or comprising a fragment thereof." Final Action at page 4. This is not a proper basis for a written description rejection of a "comprising" claim. If it were, every "comprising" claim ever written would be invalid for failing to describe every nuance of the claimed invention. Furthermore, the specification demonstrates to one skilled in the art that Applicants were in possession of the claimed genera of nucleic acid molecules.

(1) The Specification Reflects Applicants' Possession of the Claimed Invention

The purpose of the written description requirement is to ensure that the inventor had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). If a person of ordinary skill in the art would, after reading the specification, understand that the inventors had possession of the claimed invention, even if not every nuance, then the written description has been met. *In re Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584. A person of ordinary skill in the art would, after reading the present specification, understand that Applicants had possession of SEQ ID NO: 48411 and complement thereof. Applicants have provided the nucleotide

sequence required by the claims, *e.g.*, SEQ ID NO: 48411 and the complement thereof. Accordingly, Applicants have demonstrated possession of the claimed invention.

The fact that the claims at issue are intended to cover molecules that include fragments of the recited sequence, the recited sequence joined with additional sequences, or complements of the recited sequence, or nucleic acid molecules that share a claimed identity with the recited sequences, does not mean that Applicants were any less in possession of the claimed nucleic acid molecules.[7] It is well-established law that use of the transitional term "comprising" properly leaves the claims "open for the inclusion of unspecified ingredients even in major amounts." *Ex parte Davis*, 80 U.S.P.Q. 448, 450 (B.P.A.I. 1948). *Accord PPG Indus. v. Guardian Indus.*, 156 F.3d 1351, 1354, 48 U.S.P.Q.2d 1351, 1353-54 (Fed. Cir. 1998); *Moleculon Research Corp. v. CBS*, 793 F.2d 1261, 1271, 229 U.S.P.Q. 805, 812 (Fed. Cir. 1986).

The present application describes more than just the nucleotide sequence recited by the claims (SEQ ID NO: 48411). For example, the specification describes vectors comprising the claimed nucleic acid molecules (*see e.g.*, specification at page 23, line 28 through page 28, line 21) and describes how to make the nucleotide sequence and the libraries from which it was originally purified. *See, e.g.*, Example 1 at page 58, line 24 *et seq*. Furthermore, the addition of other nucleotides or detectable labels to the disclosed nucleotide sequences (*e.g.*, SEQ ID NO: 48411) is readily envisioned by one of ordinary skill in the art upon reading the present specification,[8] as described for example at page 9,

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[7] If the Examiner is arguing that no possession is shown because the precise claim language is not used in the specification, then it goes beyond what is required by the law. It is well-settled that the description of a claimed invention need not be *in ipsis verbis*. *Gentry Gallery v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *In re Alton*, 76 F.3d 1168, 1175, 37 U.S.P.Q.2d 1578, 1583 (Fed. Cir. 1996); *Martin v. Johnson*, 454 F.2d 746, 751, 172 U.S.P.Q. 391, 395 (C.C.P.A. 1972).

[8] It is established patent jurisprudence that Applicant need not teach "conventional and well-known genetic engineering techniques." *E.g., Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345, 56 U.S.P.Q.2d 1332, 1337 (Fed. Cir. 2000).

(describing sequences with labels to facilitate detection); as also described for example at page 19 (describing fusion peptide molecules encoded by the claimed nucleic acid molecules); and at page 51 (describing site-directed mutagenesis).

Moreover, the court determined, in *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1321, 63 U.S.P.Q.2d 1609, 1610 (Fed. Cir. 2002), that the written description inquiry is a factual one determined on a case-by-case basis and that, in a given disclosure, "it may well be that various subsequences, mutations, and mixtures of those sequences are also described to one of skill in the art." *Enzo*, 296 F.3d at 1326-1327, 63 U.S.P.Q.2d at 1615. Furthermore, it is well established that claims "may be broader than the specific embodiment disclosed in a specification. *Ralston-Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985) (*quoting In reRasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981).

(2) Applicants Have Described the Claimed Invention

The Examiner asserts that "the specification only provides sequences of the elected SEQ ID No:48411...", and accordingly Applicants have allegedly not adequately disclosed the claimed genera of nucleic acid molecules. Final Action at page 4. As such, the Examiner appears to require that each nucleic acid molecule within the claimed genera must be described by its complete structure. Final Action at page 4. This requirement is totally unfounded. The Federal Circuit has elucidated a test for written description wherein a genus of nucleic acids may be described by a structural feature that distinguishes members of the claimed genus from non-members of the claimed genus. *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997). Applicants have satisfied that test for written description.

In particular, Applicants have disclosed common structural features, for example the nucleotide sequence of SEQ ID NO: 48411. For example, if a particular nucleic acid

molecule contains the nucleotide sequence of SEQ ID NO: 48411, then it is a member of the claimed genus of nucleic acid molecules comprising a nucleic acid sequence of SEQ ID NO: 48411.[9] Moreover, closely related nucleic acid molecules falling within the scope of the claimed invention are readily identifiable - they either contain the nucleic acid sequence of SEQ ID NO: 48411 (or complements or fragments thereof), or share a claimed identity with SEQ ID NO: 48411 (or complements or fragments thereof), or they do not. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed throughout the specification. Thus, contrary to the Examiner's analysis, claims 11-15 are supported by an adequate written description pursuant to the requirements of 35 U.S.C. § 112, and the rejection should be reversed.

E. The Specification Provides An Adequate Written Description of the Claimed Invention: No New Matter Is Introduced

The adequacy of the written description of the claimed invention has been challenged by the Examiner because the inclusion of claim language "nucleotides 1 through 123 of SEQ ID NO: 48411" in claim 14 allegedly constitutes new matter. In order to comply with the written description requirement of 35 U.S.C. §112, Applicants must ensure that each portion of a claim is "expressly, implicitly, or inherently supported in the originally filed disclosure." MPEP §2163.05 at 2100-75; *Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). The analysis for numerical range limitations must take into account which ranges one skilled in the art would consider inherently supported by the original disclosure. *Id.* Nucleotides 1 through 123 are clearly present in Applicants'

[9] The same argument applies with equal force to every genus of the claimed nucleic acid molecules. For example, if a nucleic acid molecule contains a nucleic acid sequence that has 95% identity with nucleotides 1 through 123 of SEQ ID NO: 48411, then it is a member of the claimed genus of nucleic acid molecules having between 90% and 100% identitiy with nucleotides 1 through 123 of SEQ ID NO: 48411. *See* claim 14.

disclosure as filed. *See* SEQ ID NO: 48411 in the sequence listing. Additionally, Applicants contemplate the use of fragment nucleic acid molecules throughout their disclosure. *See e.g.*, page 8 line 28 through page 9 line 2.

The present case is analogous to *In re Wertheim*, where the range 35%-60% was permitted when the original specification had described a range between 25% and 60%. By contrast, in *Wertheim*, the range at least 35% was deemed impermissible because it included percentages not originally disclosed, *i.e.*, those percentages greater than 60% may constitute new matter. In the present case, Applicants have described nucleotides 1 through 123 of SEQ ID NO: 48411 as well as fragments thereof. Furthermore, one of skill in the art can envision a nucleic acid molecule comprising a nucleic acid sequence having between 90% and 100% sequence identity with nucleotides 1 through 123 of SEQ ID NO: 48411 or a complete complement thereof based on Applicants' disclosure. *See e.g.*, specification at page 11, lines 5-20 and the sequence listing.

In contrast, the Examiner has not provided any support for the proposition that the claim limitation of "base pairs 1 through 123 of SEQ ID NO: 48411" is not described in Applicants' specification as originally filed. It is well-settled that the description of a claimed invention need not be in *ipsis verbis*. *Gentry Gallery v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *In re Alton*, 76 F.3d 1168, 1175, 37 U.S.P.Q.2d 1578, 1583 (Fed. Cir. 1996); *Martin v. Johnson*, 454 F.2d 746, 751, 172 U.S.P.Q. 391, 395 (C.C.P.A. 1972). Thus, the Examiner has not met the burden to impose a written description rejection of claim 14. ("[t]he Examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims.") *Wertheim*, 541 F.2d at 263, 191 U.S.P.Q. at 97, M.P.E.P. §2167.04 at 2100-73.

As such, written description of the claimed invention has been satisfied, and inclusion of claim language "nucleotides 1 through 123 of SEQ ID NO: 48411" in claim 14 does not constitute new matter. Applicants respectfully submit that the rejection of claim 14 under 35 U.S.C. §112, written description should be reversed.

F. The Claimed Nucleic Acid Molecules Are Novel

The novelty of the claimed invention has been challenged by the Examiner under 35 U.S.C. §102(b) because claim 13 is allegedly anticipated by Mahairas *et al.* ("Mahairas") (Accession No. AQ451805). "It is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986). Further, "an anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice, or device." *In re Donohue*, 766 F.2d 531, 226 U.S.P.Q 619 (Fed. Cir. 1985).

In the Final Action, Claim 13 was erroneously rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Mahairas. The Examiner alleges that "absent a definition for the term 'fragment' of SEQ ID NO: 48411, one or more nucleotides are considered a fragment." Final Action at pages 6-7. However, this allegation fails to take account of the claim language, which recites a "fragment nucleic acid molecule having from about 30 to about 50 nucleotide residues, wherein said fragment nucleic acid molecule exhibits complete complementarity to a fragment of a second nucleic acid molecule having the nucleotide sequence of SEQ ID NO: 48411 or a complete complement thereof." The Examiner has not read the claims in light of Applicants' disclosure, as required, but rather has implied an interpretation, unsupported by evidence, that the claimed nucleic acid molecules encompass a fragment that "can be any nucleic acid fragment of about 30-50 bps long." Final Action at page 6. Such clearly unsupported conjecture is simply not a proper basis for an anticipation rejection.

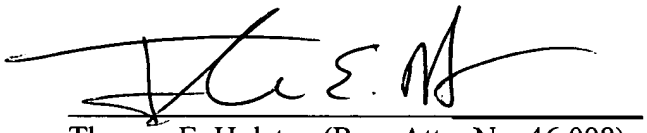
The Examiner appears to suggest that because the nucleic acid molecule of Mahairas contains a fragment that is completely complementary to nucleotides 98-118 of SEQ ID NO: 48411, Mahairas is anticipatory. The Final Action alleges that "Mahairas *et al.* contains a fragment of around 30." Final Action at page 7. Such an interpretation of the phrase "about 30 to about 50 nucleotide residues" is not in accordance with the law. *See BJ Services Co. v. Halliburton Energy Services, Inc.*, 338 F.3d 1368, 67 U.S.P.Q.2d 1692 (Fed. Cir. 2003). From the decision in *BJ Services*, the term "about" in the present claims should be given its "plain and ordinary meaning." *Id.* In *BJ Services,* the appellee attempted unsuccessfully to argue that 0.077 was "about 0.06." However, according to BJ Services, 0.077 was deemed not to give "about 0.06" its plain and ordinary meaning. *See id.* The present case is analogous to *BJ Services*. The fragment of Mahairas as cited by the Examiner contains 21 nucleotides. As in *BJ Services*, this 21 nucleotide base pair fragment fails to give "about 30 nucleotides" its "plain and ordinary meaning." *Id.*

Whatever else Mahairas may teach or suggest, it does not teach or suggest a substantially purified nucleic acid molecule comprising a fragment nucleic acid molecule having from about 30 to about 50 nucleotide residues, wherein said fragment nucleic acid molecule exhibits complete complementarity to a fragment of a second nucleic acid molecule having the nucleotide sequence of SEQ ID NO: 48411 or a complete complement thereof. The law requires that each and every element of a claimed invention is disclosed within a single prior art reference. *In re Bond*, 15 U.S.P.Q.2d 1566, 1567 (Fed. Cir. 1990). As such, the rejection of claim 13 as anticipated under 35 U.S.C. §102(b) by Mahairas is improper and should be reversed.

CONCLUSION

In view of the foregoing, it is respectfully requested that the Board of Patent Appeals and Interferences reverse the Rejections and that the subject application be allowed forthwith.

Respectfully submitted,



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APPENDIX A

11. A substantially purified nucleic acid molecule comprising a fragment nucleic acid molecule having from about 30 to about 50 nucleotide residues of a nucleic acid molecule having the nucleotide sequence of SEQ ID NO: 48411.

12. A substantially purified nucleic acid molecule comprising a fragment nucleic acid molecule having from about 50 to about 100 nucleotide residues of a nucleic acid molecule having the nucleotide sequence of SEQ ID NO: 48411.

13. A substantially purified nucleic acid molecule comprising a fragment nucleic acid molecule having from about 30 to about 50 nucleotide residues, wherein said fragment nucleic acid molecule exhibits complete complementarity to a fragment of a second nucleic acid molecule having the nucleotide sequence of SEQ ID NO: 48411 or a complete complement thereof.

14. A substantially purified nucleic acid molecule having between 90% and 100% sequence identity with nucleotides 1 through 123 of SEQ ID NO: 48411 or a complete complement thereof.

15. The substantially purified nucleic acid molecule of claim 14, wherein said substantially purified nucleic acid molecule has between 99% and 100% sequence identity with nucleotides 1 through 123 of SEQ ID NO: 48411 or a complete complement thereof.

16. A substantially purified nucleic acid molecule according to claim 15, wherein said nucleic acid molecule has the nucleic acid sequence of SEQ ID NO: 48411 or the complete complement thereof.

Image

AF/1631

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April 1, 2004

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Commissioner for Patents
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Art Unit 1631
Examiner: S. Zhou
Conf. No.: 9497

Re: U.S. Patent Application Serial No. 09/684,016 filed October 10, 2000
Appellants: David K. KOVALIC *et al.*
Title: Annotated Plant Genes
Atty. Docket: 16517.031

Sir:

Transmitted herewith for appropriate action by the U.S. Patent and Trademark Office (PTO) are the following documents:

1. Appellants' Amended Brief, with attached Appendix A (in triplicate); and
2. Return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier.

In the event that extensions of time beyond those petitioned for herewith are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned. Appellants do not believe that any fees are due in conjunction with this filing. However, if any fees under 37 C.F.R. § 1.16 or § 1.17 are required in the present application, including any fees for extensions of time, then the Commissioner is hereby authorized to charge such fees to Arnold & Porter LLP Deposit Account No. 50-2387, referencing docket number 16517.031. A duplicate copy of this letter is enclosed.

Sincerely,

David R. Marsh by Milan M. Vinnola

David R. Marsh (Reg. No. 41,408)
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Enclosures